

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP,
ASTRAZENECA UK LIMITED

Plaintiffs,

v.

HANDA PHARMACEUTICALS, LLC and
JOHN DOE ENTITY

Defendants.

Civil Action No. 08-3773 (JAP)
Civil Action No. 08-5328 (JAP)
Civil Action No. 08-5997 (JAP)

ASTRAZENECA PHARMACEUTICALS LP,
ASTRAZENECA UK LIMITED

Plaintiffs,

v.

ACCORD HEALTHCARE, INC., and
INTAS PHARMACEUTICAL LTD.,

Defendants.

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Civil Action No. 08-~~4808~~ (JAP)
Civil Action No. 09-619 (JAP)

ASTRAZENECA PHARMACEUTICALS LP,
ASTRAZENECA UK LIMITED

Plaintiffs,

v.

BIOVAIL LABORATORIES INTERNATIONAL
SRL, BIOVAIL CORPORATION and BTA
PHARMACEUTICALS, INC.,

Defendants.

Civil Action No. 09-128 (JAP)

ASTRAZENECA PHARMACEUTICALS LP,
ASTRAZENECA UK LIMITED

Plaintiffs,

v.

ANCHEN PHARMACEUTICALS, INC.

Defendant.

Civil Action No. 10-1835 (JAP)

ASTRAZENECA PHARMACEUTICALS LP,
ASTRAZENECA UK LIMITED

Plaintiffs,

v.

OSMOTICA PHARMACEUTICAL
CORPORATION,

Defendant.

Civil Action No. 10-4203 (JAP)

ASTRAZENECA PHARMACEUTICALS LP,
ASTRAZENECA UK LIMITED

Plaintiffs,

v.

TORRENT PHARMACEUTICALS LIMITED
and TORRENT PHARMA INC.,

Defendants.

Civil Action No. 10-4205 (JAP)

Civil Action No. 10-4971 (JAP)

OPINION

PISANO, District Judge.

Presently before the Court is a Motion for Clarification and Reconsideration filed by Defendants Torrent Pharmaceuticals Limited and Torrent Pharma Inc. (collectively, “Torrent”), pursuant to Local Civil Rule 7.1(i). In an Opinion dated November 30, 2010, the Court addressed its construction of the disputed claim terms of United States Patent No. 5,948,437, titled “Pharmaceutical Compositions Using Thiazapine.” Defendant Torrent requests the Court clarify that “the Court’s adoption of Astra’s construction of the term ‘gelling agent’ included Astra’s concession at the Markman hearing that the term ‘gelling agent’ is what causes the [invention’s] sustained release.” Torrent Br. at 1. In addition, Torrent asks the Court to reconsider its finding that “nowhere in the intrinsic evidence is there a specific disclaimer of polyvinylpyrrolidone (PVP) as a ‘gelling agent.’” Opinion 8. For the reasons below, Torrent’s motion is denied.

I. Torrent’s Motion for Clarification

Torrent requests that the Court “clarify” its construction of the term “gelling agent,” which the Court in the November 30 Opinion construed as follows: “Any substance which forms a gel when in contact with water.” This was the construction of “gelling agent” originally proposed by AstraZeneca, along with Accord, Biovail, Anchen and Osmotica. Opinion 7. At oral argument, however, AstraZeneca amended its proposed construction from the one it originally proposed. Specifically, in an attempt to narrow the dispute over the construction of “gelling agent,” AstraZeneca stated at the *Markman* hearing that it agreed with Torrent that the construction of gelling agent should include language stating that the gelling agent is what provides the sustained release.

The Court's *Markman* Opinion is clear that, although it states that the Court adopted "Astra's" proposed construction, the proposed construction the Court adopted for "gelling agent" was that originally proposed by AstraZeneca, Accord, Biovail, Anchen and Osmotica. *See* Opinion at 7 ("Astra, Accord, Biovail, Anchen, and Osmotica propose that the claim be construed as "any substance which forms a gel when in contact with water."). Torrent's motion, however, couched as one for "clarification," now asks the Court to include AstraZeneca's "concession" (*i.e.*, its later-proposed construction) in the Court's construction of "gelling agent." The Court's Opinion and its construction of the term gelling agent is clear. No further clarification is warranted. Torrent's motion is denied.

II. Torrent's Motion for Reconsideration

Torrent also asks the Court to reconsider its holding that "nowhere in the intrinsic evidence is there a specific disclaimer of PVP as a "gelling agent." In its analysis of the construction of "gelling agent," the Court found that "nowhere in the intrinsic evidence is there a specific disclaimer of PVP as a 'gelling agent.'" Opinion 8.

A Motion of Reconsideration places a heavy burden on the movant. This extraordinary remedy "...is only appropriate when one of the following three grounds for relief is established: "(1) 'an intervening change in the controlling law has occurred; (2) evidence not previously available has become available; or (3) it is necessary to correct a clear error of law or prevent manifest injustice.'" *Daewoo Elecs. Am., Inc., v. T.C.L. Indus. (H.K) Holdings Ltd.*, 2010 WL 4624051, *1 (D.N.J. Nov. 4, 2010) (citing *Carmichael v. Everson*, 2004 WL 1587894, *1 (D.N.J. May 21, 2004) (quoting *Database America, Inc. v. Bellsouth Advertising & Pub. Corp.*, 825 F. Supp. 1216, 1220 (D.N.J. 1993); *North River Ins. Co. v. CIGNA Reinsurance Co.*, 52 F.3d 1194, 1218 (D.N.J. 1993)). "[M]ore than a mere recapitulation of the cases and arguments considered

by the court before rendering its original decision” is required to fulfill the burden of the moving party. *Id.* The movant must show more than a disagreement with the Court’s decision. *Id.* (quoting *G-69 v. Degnan*, 748 F. Supp. 274, 275 (D.N.J. 1990)).

The Court finds that Defendant Torrent has not met the burden of establishing sufficient grounds for reconsideration. There is no argument that an intervening change in controlling law occurred or that new evidence has become available, rather Torrent offers nothing more than “recapitulation of the cases and arguments considered by the [C]ourt before rendering its original decision.” *Id.* For example, Torrent argues that the Court has misinterpreted *SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc.*, 242 F.3d 1337 (Fed. Cir. 2001) (holding that patents do not cover certain device configurations when they were specifically recognized and disclaimed in the patents) and has overlooked three disclaimers in the intrinsic evidence.

Moreover, the Court did not “misinterpret the requirements of *SciMed*.” Torrent Br. at 3. *SciMed* held that certain features are not covered by the patent when they are “specifically recognized and disclaimed” by the patents. *Id.* at 1347. In *SciMed*, the patent-in-suit included a written description that “all embodiments of the present invention” contain a coaxial lumen and expressly distinguished the double lumen configurations by discussing the disadvantages that were overcome by the coaxial lumens used in the patented invention. *Id.* at 1344. The Court distinguished *SciMed* from this case in the November 30 Opinion. Unlike *SciMed*, where “[e]ach of the *SciMed* patents specifically recognized and disclaimed the dual lumen structure, making clear that the patentee regarded the dual lumen configuration as significantly inferior to the coaxial lumen configuration used in the invention,” *id.*, here PVP is expressly listed as one of a number of exemplary “gelling agents.”

Torrent further argues the Court ignored three specific disclaimers of PVP as a gelling agent: (1) in Claim 9 of the patent states that at about 1-15% PVP is an additional pharmaceutically acceptable excipient, (2) in the “immediate release” formulation of Example 12 contains 5% PVP, and (3) in AstraZeneca’s provisional patent application PVP is listed as a binder.

In AstraZeneca’s patent, PVP is expressly listed as a gelling agent. Although PVP in certain formulations can also be used as an excipient, this is no indication that PVP cannot also be used as a gelling agent. In addition, even though PVP can be used in an immediate release formulation that does not mean it cannot also be used as a gelling agent in other formulations. Finally, the fact that PVP may be used as a binder, as described in the provisional application, is not a disclaimer of PVP as a gelling agent.

Accordingly, because Defendant Torrent has not met the high burden of establishing adequate grounds for reconsideration, this motion is denied.

/s/ JOEL A. PISANO
United States District Judge

Dated: February 17, 2011